REMARKS

In the Official Action dated October 22, 2003, claim 23 has been rejected under 35 U.S.C § 112, as allegedly indefinite. Claims 22-23, 25-28 and 30 have been rejected under 35 U.S.C § 103 as allegedly unpatentable over Elliott *et. al.*, WO 00/50380 and Busch *et. al.*, WO 97/42190 or Urban, U.S. Patent No. 5,359,068.

Claims 1-21, 24 and 29 have been cancelled without prejudice. The Applicant reserves the right to file a continuing application drawn to the subject matter of the cancelled claims.

Claims 23, 25-28 and 30 have been amended to correct claim dependency. In addition, claim 22 has been amended to remove a term objected to by the Examiner to expedite prosecution. No limiting amendments were made to the claims, and no amendments were made because of prior art.

This Response addresses each of the Examiner's rejections and objections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claim 23 has been rejected under 35 U.S.C § 112, as allegedly indefinite. The Examiner contends that Claim 23 depends from itself and that the phrase "i.e." renders the claim indefinite.

In response, the Applicant has amended claim 23 to reflect proper dependency on claim 22. In addition, the Applicant has deleted the phrase "i.e." from claim 23. Accordingly, this rejection has been obviated, and removal thereof is respectfully requested.

Claims 22-23, 25-28 and 30 have been rejected under 35 U.S.C § 103, as allegedly unpatentable over Elliott *et. al.*, WO 00/50380 and Busch *et. al.*, WO 97/42190 or Urban, U.S. Patent No. 5,359,068. The Applicant respectfully traverses.

The claims of the present invention relate to a method of treating anxiety or depression, obsessive disorder, and psychosis in a mammal, comprising administering to said mammal: (a) a compound that exhibits activity as an SRI antidepressant, or a pharmaceutically acceptable salt thereof; and (b) atypical antipsychotic or pharmaceutically acceptable salt thereof; wherein the active agents "a" and "b" above are

present in amounts that render the combination of the two agents effective in treating, respectively, anxiety or depression, obsessive compulsive disorder, and psychosis.

Elliot *et. al.* disclose methods of treating depression, anxiety disorders, and obsessive-compulsive disorders, etc., in a mammal comprising administering to said mammal in need of such treatment SRI inhibitors such as [2-(3,4-Dichlorophenoxy)-5-fluorobenzyl]-methylamine. Although Elliot *et al.* disclose using SRI inhibitors to treat depression, anxiety disorders, and obsessive-compulsive disorders, Elliot *et. al.* do not disclose or suggest combining an atypical antipsychotic with an SRI antidepressant. Furthermore, Elliot et. al. do not motivate one skilled in the art to combine an atypical antipsychotic with an SRI inhibitor. Accordingly, the claimed invention is patentable over Elliot *et. al.*

Busch *et. al.* and Urban each disclose using ziprasidone to treat anxiety. However, neither Busch *et. al.* nor Urban disclose or suggest combining an SRI antidepressant and an atypical antipsychotic for treating anxiety or depression, obsessive disorder, and psychosis in a mammal. Furthermore, neither Busch *et. al.* nor Urban motivate one skilled in the art to combine an SRI antidepressant and an atypical antipsychotic for treating anxiety or depression, obsessive disorder, and psychosis in a mammal. Accordingly, the claimed invention is patentable over Busch *et. al.* and Urban.

In order to establish a *prima facie* case of obviousness, there must be motivation to modify the prior art, and this motivation must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. In the instant case, there is no motivation or teaching in either Elliot *et. al.*, Busch *et. al.*, or Urban that would have suggested the desirability of combining an SRI antidepressant and an atypical antipsychotic for treating anxiety or depression, obsessive disorder, and psychosis in a mammal.

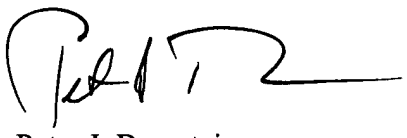
The Examiner's reliance on *In re Kerkhoven* is misplaced. The Court in *In re Kerkhoven* held that it is *prima facie* obvious to combine two compositions, each of which is taught by prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In contrast, the claimed

invention discloses combining an SRI antidepressant, which is used to treat depression, with an atypical antipsychotic, which is used to treat psychosis. Since the claimed invention combines two agents wherein each agent has a different therapeutic purpose, *In re Kerkoven* does not apply. Accordingly, the requisite motivation in the references cited by the Examiner supporting the modification needed to arrive at the claimed invention is not found.

Since the requisite motivation supporting the modification needed to arrive at the claimed invention is lacking, a *prima facie* case of obviousness has not been established. Accordingly, the Applicant respectfully requests reconsideration and withdrawal of this rejection.

Thus, in view of the forgoing amendments and remarks, the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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